



Federal Communications Commission
Washington, D.C. 20554

November 20, 2014

DA 14-1666

Mr. Ventzeslav P. Iordanov
Principal System Architect
Director Quality Assurance & Regulatory Affairs
High Tech Campus 10
5656 AE Eindhoven
Netherlands

Re: ET Docket No. 14-84

Dear Mr. Iordanov:

The Office of Engineering and Technology (OET), by this letter, is granting the request of Medimetrics for waiver of Section 15.231(b) of the Commission's rules to allow it to obtain FCC certification for marketing its medical device trademarked as IntelliCap FR Portable Unit (Portable Unit), which is a part of the IntelliCap FR product system.¹

In the request you filed March 19, 2014, you state that the IntelliCap FR system is an oral drug delivery device used for *in-vivo* measurement of pH and temperature in the gastrointestinal (GI) tract of humans and larger mammals to facilitate delivery of drugs in defined sections of the GI tract as a research tool for premarket drug research.² You explain that this tool permits drug developers to rapidly profile new drug candidates and drug formulations to meet patient's needs.³

You explain that the Portable Unit relays control signals and related communications between a Central Control Unit (CCU), *i.e.* typically a laptop computer loaded with the IntelliCap software, and an ingested capsule that transmits real-time data to the Portable Unit. The ingested capsule generally has an operational lifetime of 48-72 hours. The Portable Unit typically is housed in a belt pouch that is placed around the waist of the test subject. It sends control signals to the ingested capsule and receives data from the capsule in the 433 MHz band. The Portable Unit communicates with the CCU in the 2.4 GHz band.⁴

You state that the Portable Unit communication to the CCU complies with the Commission's Part 15 rules.⁵ You explain that the Portable Unit, when receiving a data signal from the capsule in the 433MHz

¹ See Medimetrics Personalized Drug Delivery B.V., Request for Waiver of Section 15.231(b) of the Commission's Rules (Power Limits Breach) to Permit the Operation of a Portable Unit as a Transmitter (concerning Very Occasional Short Transmission of a Command to an Orally Introduced Capsule, Used as a Research Tool in the Process of Development of New Drugs (Request) dated March. 19, 2014.

² See Request at 4 through 6.

³ See Request at 3.

⁴ See Request at 7.

⁵ *Id.* at 8. The IntelliCap capsule portion of the system has received FCC Certification under Part 15.231(e) with the FCC ID YDVINTELLICAP-CI.

frequency band, also complies with the Commission's Part 15 rules⁶ and it is only the transmission of the signal from the Portable Unit to the capsule that exceeds the emission limits for unlicensed intentional radiators contained in section 15.231(b) of the Commission's rules.⁷ Specifically, Section 15.231(b) limits the field strength of emissions from intentional radiators operating in the 433 MHz band to 10959 $\mu\text{V}/\text{m}$ measured at a distance of 3 meters (0.022 mW ERP).⁸ You state that the Portable Unit transmission power ranges up to 84304 $\mu\text{V}/\text{m}$ measured at 3 m (1.3 mW ERP) when transmitting at 433 MHz band to the capsule. You request that we waive Section 15.231(b) to allow current and future generations of the Portable Unit to operate with emissions not to exceed 84304 $\mu\text{V}/\text{m}$ measured at 3 meters (1.3 mW ERP).⁹

In your request, you state that the choice of the 433 MHz frequency band is driven primarily by the capsule's (small) size and the consequent need for a small antenna. You further state substantial power is needed for the Portable Unit to communicate through body tissue to the capsule due the small size of the capsule and its antenna.¹⁰ In support of your request, you state that the Portable Unit is to be used only in a controlled environment (*i.e.*, commercial research clinic or research hospital), where the possibility of interference with other authorized users of the 433 MHz band is highly unlikely. You state that when the Portable Unit is located outside of the controlled environment, it is to be used only as a receiver for transmissions from the capsule so that emissions in excess of the Commission's rules would not occur.¹¹ You state that Portable Unit transmission time for each data stream will be less than 10.5 milliseconds and sent to the capsule non-periodically and not more than 5 times in a 72-hour period, with at least several hours pause in between each transmission. You state that due to the reasons stated above, *i.e.* geographical location restriction and very low duty cycle, the Portable Unit is highly unlikely to cause harmful interference to authorized operations in the 433 MHz band, such as amateur and federal government radar operations.¹²

In further support of your request, you state that granting Medimetrics waiver for its Portable Unit will be in the public interest because it would enable the IntelliCap FR system to offer a valuable medical tool for research in the pharmaceutical industry. It does so by combining diagnostic functionalities to determine anatomical location with the capability to release a drug formulation (either liquid or solid), which offers the opportunity to rapidly profile new drug candidates and drug formulations to meet patient's needs.¹³ You contend that beyond its role in pharmaceutical drug profiling and formulation development, the IntelliCap FR product system also offers the potential of therapeutic intervention. Examples include treatment of gastrointestinal diseases such as Crohn's disease or gastrointestinal cancer, as well as therapeutic agents that require high concentrations in the portal system such as insulin, gastrointestinal hormones and chemotherapeutics for malignant liver disease.¹⁴

⁶ *Id.* at 7.

⁷ *Id.* at 9.

⁸ 47 C.F.R. Section 15.231(b).

⁹ See Request at 10. You further state that the MICS 401 MHz band was considered but not chosen due to the listen-before-talk requirements.

¹⁰ *Id.* at 6.

¹¹ *Id.* at 9.

¹² *Id.* at 9.

¹³ *Id.* at 3.

¹⁴ *Id.* at 3.

The Commission issued a Public Notice (DA 14-769) soliciting comments on Medimetrics's request on June 4, 2014. No comments or reply comments were filed in response.

We are authorized to grant a waiver under Section 1.3 of the Commission's rules if the petitioner demonstrates good cause for such action.¹⁵ Good cause, in turn, may be found and a waiver granted, "where particular facts would make strict compliance inconsistent with the public interest."¹⁶ To make this public interest determination, the waiver cannot undermine the purposes of the rule, and there must be a stronger public interest benefit in granting the waiver than in applying the rule.¹⁷

Based on the Portable Unit's intended use and negligible interference potential, presented in this request, we conclude that a waiver permitting the Medimetrics Portable Unit device to operate in the 433 MHz band with the emissions limited to 84304 $\mu\text{V/m}$ measured at 3 meters (1.3mW ERP) is warranted. We believe that the purpose underlying the emissions limit in the Rules (i.e., preventing harmful interference) would not be undermined by applying the requested limit to current and future generations of the Portable Unit.

The only non-federal licensed service in this band is for amateur radio operations. The band 420-450 MHz is used by the military and other federal agencies for a number of important radar applications, multi-function position-location communications systems, and test range telecommand and flight termination systems making the band essential to national security. The band 420-450 MHz is used extensively by the military agencies for land-based, shipborne, and airborne radar systems to perform important national security functions. The physics of radio propagation make the band excellent for long-range radar search and surveillance operations, and the associated target tracking. The band is used for long-range search and surveillance radars to detect and track ballistic missiles and aircraft, and to catalog objects in space. The military agencies use the band 420-450 MHz for the multi-function Position Location Reporting System (PLRS) and the modernized Enhanced Position Location Reporting System (EPLRS). EPLRS is a data communications network that enables the rapid determination of the locations of all units in the network. EPLRS also has communications and navigational capabilities in addition to the position location feature. The EPLRS and its airborne version, the AEPLRS, are critical to the operations and safety of military forces. The band 420-450 MHz is also used for command control and flight termination functions at numerous missile and rocket launch and test ranges.¹⁸

Given the brief and limited transmissions for each treatment, as well as the locations of use and the likely limited number of devices that will be deployed and in use at any time, it is extremely unlikely that

¹⁵ 47 C.F.R. § 1.3. See also *ICO Global Communications (Holdings) Limited v. FCC*, 428 F.3d 264 (D.C. Cir. 2005); *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164 (D.C. Cir. 1990); *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969).

¹⁶ *Northeast Cellular, Id.* at 1166; See also *ICO Global Communications, Id.* at 269 (quoting *Northeast Cellular*); *WAIT Radio, Id.*, 1157-59.

¹⁷ See, e.g., *WAIT Radio, Id.* at 1157 (stating that even though the overall objectives of a general rule have been adjudged to be in the public interest, it is possible that application of the rule to a specific case may not serve the public interest if an applicant's proposal does not undermine the public interest policy served by the rule); *Northeast Cellular, Id.* (stating that in granting a waiver, an agency must explain why deviation from the general rule better serves the public interest than would strict adherence to the rule).

¹⁸ Additional information on federal use in the 420-450 MHz band is available at www.spectrum.gov.

amateur and federal radio communication systems will experience harmful interference from the operation of these devices at the power levels and operating conditions indicated. The Medimetrics devices operating under our Part 15 rules must accept any interference that occurs from amateur and federal systems.¹⁹ We also believe that granting this waiver will be consistent with previously-established precedent wherein the Commission has waived field strength requirements for medical devices.²⁰ We also conclude that grant of a waiver to Medimetrics for the Portable Unit, will serve the public interest by providing a medical tool that can facilitate the development of more effective orally-administered drugs for certain serious medical conditions. In turn, this could enhance the quality of life for countless members of the public and result in lower health care costs.

This waiver applies only to current and future generations of this specific IntelliCap FR Portable Unit used for drug development research, and is not to be considered generally applicable to other uses or other devices. Operation under this waiver is subject to the conditions that the Portable Unit will not transmit outside a controlled environment and that its transmission shall be less than 10.5 ms in duration and that the number of transmissions for each application is limited to 5 within a 72 hour period with at least three hours of separation between transmissions. In accordance with Section 15.5(b) of the Commission's Rules, operation of IntelliCap FR Portable Unit is also subject to the conditions that no harmful interference is caused and that interference must be accepted from other users of the spectrum.

Accordingly, pursuant to the delegated authority in Sections 0.31, 0.241, and 1.3 of the Commission's Rules, 47 C.F.R. §§ 0.31, 0.241, 1.3, we waive the requirements of Section 15.231(b) of our Rules to allow Medimetrics to obtain FCC certification for and to market its IntelliCap FR Portable Unit device that operates in the transmit frequency band 433 MHz, with external emissions not to exceed 84304 $\mu\text{V/m}$ at a measurement distance of 3 meters (1.3mW ERP) for use as described in this letter. With this action, the above-captioned proceeding IS TERMINATED.

Medimetrics is directed to include a copy of this waiver grant when submitting an application for equipment authorization for the subject device.

Sincerely,

Julius P. Knapp
Chief
Office of Engineering and Technology

¹⁹ See 47 C.F.R. § 15.5(b). Operation of an intentional, unintentional, or incidental radiator is subject to the conditions that no harmful interference is caused and that interference must be accepted that may be caused by the operation of an authorized radio station, by another intentional or unintentional radiator, by industrial scientific and medical (ISM) equipment, or by an incidental radiator. This information is required to be displayed under the labeling requirements in the 47 C.F.R. § 15.19.

²⁰ See Letter from Julius P. Knapp, Chief, Office of Engineering and Technology, FCC, to Mitchell Lazarus, Counsel for EnteroMedics Inc., 24 FCC Rcd 13795, 13796 (OET 2009). *See also* Letter from Julius P. Knapp, Chief, Office of Engineering and Technology, FCC, to Tritt and Pham, Counsel for Second Sight Medical Products, Inc., 26 FCC Rcd 16170 (OET 2011).